

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA and NEW YORK : Case No.: CV 12-5142  
STATE, ex rel. IRINA GELMAN, DPM, :  
Plaintiffs, :  
v. :  
GLENN J. DONOVAN, DPM, NEW YORK CITY :  
HEALTH and HOSPITALS CORPORATION, and :  
PHYSICIAN AFFILIATE GROUP OF NEW YORK, :  
P.C., :  
Defendants. :  
-----x

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS  
THE AMENDED COMPLAINT**

Joseph V. Willey  
Alan J. Brudner  
Katten Muchin Rosenman LLP  
575 Madison Avenue  
New York, New York 10022  
Phone: (212) 940-8800  
Fax: (212) 940-8776  
joseph.willey@kattenlaw.com  
alan.brudner@kattenlaw.com

*Attorneys for Defendants*

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Defendants Dr. Glenn J. Donovan, DPM (“Dr. Donovan”), Physician Affiliate Group of New York, P.C. (“PAGNY”), and the New York City Health and Hospitals Corporation (“NYC Health + Hospitals,” together, “Defendants”) submit this memorandum of law in support of their motion to dismiss the First Amended Complaint (“Amended Complaint” or “Am. Cplt.”) in this *qui tam* action because, as to each Defendant, it (i) fails to plead fraud with the particularity required by Rule 9(b), and (ii) fails to state a claim on which relief can be granted, as required by Rule 12(b)(6).

#### PRELIMINARY STATEMENT

The crux of the False Claims Act (“FCA”) (and its New York State analog (“NYFCA”)) is that it forbids “knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval” to the Government. 31 U.S.C. § 3729(a)(1)(A). The submission of a false claim is the *sine qua non* of an FCA claim; yet the Amended Complaint does not identify a single bill as having been submitted by, or on behalf of, any Defendant. Instead, the Amended Complaint cites a plethora of regulations and agency manuals that are either inapplicable, misconstrued, or misapplied to the alleged facts. These references have been combined in a lengthy but specious pleading that fails to state a plausible FCA claim, much less one with sufficient particularity. By failing to refer to any actual bills presented for payment, the Amended Complaint also necessarily fails to identify any specific representations made by any Defendant about goods or services provided. It fails to allege facts from which knowledge of a false claim can be attributed to any Defendant. It impermissibly groups all three Defendants together in every claim, without differentiation, despite important legal and factual distinctions among them. It bundles Medicaid and Medicare together despite different rules, applicability, and coverage. It alleges a conspiracy without a whiff of an allegation about an agreement.

The Relator, Irina Gelman (“Relator”), camouflages her fatal omission of the required

“who, what, where, when and why” of any specific false bills by alleging that all three Defendants followed “Standard Operating Procedures” (“SOPs”) that must have led to the fraudulent billing of Medicare and Medicaid. These alleged SOPs are nowhere defined, identified, or attributed. Nothing is said about what they say, how they work, to whom they apply; nothing is said about them at all. And since references to these unspecified, undefined SOPs have been inserted into the Amended Complaint precisely where the original complaint made the same allegations on the basis of “information and belief,” it is obvious that the most plausible thing about these SOPs is that they are words being used to mask the fact that Relator knows nothing about any of the three Defendants’ billing processes or any actual false claims.

The United States Attorney’s Office for the Eastern District of New York (“USAO”) and the New York State Attorney General (“NYAG”) investigated Relator’s allegations for more than two years after her original complaint was filed in October 2012, and a second time when her Amended Complaint was filed in July 2015. Both offices twice declined to intervene. Relator is now pursuing this as a *qui tam* action.

The Amended Complaint purports to allege three primary theories of liability: (1) that Dr. Donovan was absent when his presence was required; (2) that bills for hospital and professional services were improper because two PMSR residents lacked limited residency permits (LRPs) required by New York State Education Law; and (3) that certain violations were concealed from the Council on Podiatric Medical Education (“CPME”) in order to maintain that body’s approval of the program, rendering claims for Medicare and Medicaid funding for Graduate Medical Education (“GME”) false. None of these theories is pled with sufficient particularity to state an FCA claim; moreover, none can possibly state a claim against all three Defendants, yet all three theories are alleged against all three Defendants with nothing to distinguish between them.

1. **Dr. Donovan's Allegedly Insufficient Presence Cannot Form the Basis of These FCA Claims.**

The premise underlying the first set of allegations, that Dr. Donovan was required to be physically present when various procedures were performed by podiatry residents at CIH, is derived from a mischaracterization and misapplication of Medicare's Teaching Physician Rule, 42 C.F.R. § 415.172. This rule did not mandate Dr. Donovan's physical presence when services were provided. Instead, it says only that *if* a physician is going to seek payment from *Medicare* for *professional services* furnished in the context of care involving residents, *then* he must be physically present for the key portions of the provision of that care. Relator sets forth no factual basis from which to conclude that payment was ever sought for Dr. Donovan's professional services – properly or improperly – apart from the aforementioned amorphous SOPs.

With respect to billing *Medicaid* for professional services, the Amended Complaint is all the more flawed – the professional services of a podiatrist in a hospital setting are *never reimbursable* as Medicaid covered services in New York, because podiatrists are not considered “physicians” under New York State law. Thus, seeking reimbursement for Dr. Donovan’s professional services at CIH would have been pointless.

Moreover, hospitals and physicians generally bill separately for each of the respective aspects of health care services they provide, under different sets of rules, and the Teaching Physician Rule has no applicability to a *hospital's* billing for *hospital* services (which is designed to reimburse the hospital for its personnel and other costs in maintaining and administering the facility). Accordingly, the Teaching Physician Rule can have no bearing on whether NYC Health + Hospitals would be entitled to payment had bills for CIH hospital services been submitted.

**2. Podiatry Residents' LRP Obligations Are Immaterial to Payment for Hospital and Professional Services.**

New York Education Law does require that podiatry residents in hospital settings hold LRPs. However, Relator fails to allege, as she must under recent United States Supreme Court precedent, facts tending to show that Medicare or Medicaid in New York would refuse to reimburse for hospital or professional services where a resident lacking an LRP participated in the services provided. Nowhere is a resident's compliance with this *Education Law* requirement explicitly or implicitly established as a condition of *Medicare* or *Medicaid* payment for hospital or a podiatrist's professional services in which those residents participate. Nowhere does Relator allege that the claim forms allegedly submitted for such services identified the residents involved in a particular patient's care. A resident's lack of an LRP simply cannot convert into a false claim a bill for hospital or professional services in which that resident had some involvement as part of his training.

**3. The CPME Approved the PMSR Program Knowing of its Alleged Deficiencies.**

The third main theory of the Amended Complaint is that Defendants concealed various programmatic violations from the CPME, and that the CPME would have withdrawn its approval of the PMSR program had it been aware of these violations. Even assuming that the underlying violations occurred, this claim is wildly speculative. The CPME, an autonomous private accrediting body for podiatric medical education, has procedures to address compliance concerns which provide for a spectrum of potential remedies that are less onerous than withdrawing its approval of a residency program. These range from taking no action to imposing a probationary period in which to remedy deficiencies. In fact, the Amended Complaint states that Relator's core allegations were actually brought to the CPME's attention in 2012 and reviewed; yet the CPME took no adverse action. Relator's allegations that the PMSR program should not have

been approved, or should be considered the equivalent of unapproved for purposes of GME funding, disregards the review that the CPME actually performed. Relator's attempt to stretch this allegation into an FCA claim by alleging that to obtain government funding, Defendants made implicit false representations that the PMSR program was "approved" by the CPME, is fantasy; such a representation would have been true and accurate, and would remain so today.

In short, none of the allegations<sup>1</sup> in the Amended Complaint come close to meeting the standards for pleading an FCA claim, or for doing so with the requisite particularity. Defendants urge the Court to dismiss the Amended Complaint with prejudice.

#### **STATEMENT OF THE CASE**

##### **A. The Parties**

NYC Health + Hospitals is a public benefit corporation created by the New York State legislature in 1969 for the purpose of administering New York City's public hospitals. N.Y. Unconsol. Laws § 7384. It is the largest municipal healthcare system in the nation and its mission is "[t]o extend equally to all New Yorkers, regardless of their ability to pay, comprehensive health services of the highest quality in an atmosphere of humane care, dignity and respect." NYC Health + Hospitals, Mission & Values, <http://www.nychealthandhospitals.org/hhc/html/about/About-MissionVisionValues.shtml>.

CIH is a hospital operated by NYC Health + Hospitals. CIH has no separate corporate existence and is not a defendant in this action. CIH has a PMSR program. Am. Cplt. ¶ 4. The PMSR program was approved by the CPME for the period of time relevant to this action, and continues to be approved. As part of their training, residents in the PMSR program participate in

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<sup>1</sup> Relator also makes miscellaneous other faulty and deficient claims, including that of an alleged conspiracy to violate the FCA (with no factual details or allegations of any agreement) and a claim that NYC Health + Hospitals is liable under the NYFCA (under which it is not a "person" subject to suit).

the provision of podiatric services at CIH.

Dr. Donovan is, and was at all relevant times, Director of the PMSR program at CIH. Am. Cplt. ¶ 7. Dr. Donovan and most of the doctors at CIH are employees of PAGNY, a professional corporation that employs a large group of health care professionals. The Amended Complaint alleges that beginning in about 2010, “PAGNY assumed professional staffing and billing responsibilities at several [NYC Health + Hospitals] hospitals, including CIH.” Am. Cplt. ¶ 10. PAGNY is not specifically referenced anywhere else in the Amended Complaint.

In or about July 2010, Relator enrolled as a resident in the PMSR program at CIH. Am. Cplt. ¶ 6. Between July 2010 and May 2012, as part of the PMSR program, Relator assisted in providing outpatient services at the CIH podiatry clinic and inpatient and emergency services at CIH. *Id.*; Am. Cplt. ¶ 101.

## **B. The Regulatory Framework**

### **1. Medicare**

Medicare is a federal program established under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395, *et seq.*, which provides health insurance to individuals age 65 and older and to certain disabled individuals. Medicare covers services provided in a hospital setting as well as direct patient care services furnished by physicians. *See* 42 U.S.C. §§ 1395d(a)(1), 1395x(s)(1), (2)(B). When physicians furnish direct patient care services in a hospital setting, Medicare makes separate payments to the hospital and to the physician. *See* 42 U.S.C. §§ 1395l(t), 1395ww(d), 1395w-4(a). There are different rules that apply to Medicare payments for hospital and physician direct patient care services, intended to ensure that the physician is not paid for the same services for which the hospital is otherwise reimbursed.

Medicare payments are made to hospitals to cover two primary groups of costs: hospital services and GME. Hospital services covered by Medicare are reimbursed upon submission of

individual claims for inpatient stays, and for outpatient clinic and emergency room visits. *See* 42 C.F.R. §§ 412.2(a), 419.2(a). The associated hospital rates are intended to reimburse the hospital for personnel and other costs incurred in maintaining the facility, including the costs of medical supplies and equipment, and the labor costs associated with the hospitals' clinical and technical staff. *See* 42 C.F.R. §§ 412.2(c),(d), 419.2(b).

Separately, Medicare GME payments are intended to reimburse hospitals with approved residency programs (such as the PMSR at CIH) for the costs directly associated with those programs, including resident salaries and benefits, physician teaching and supervision of residents, and administration of the programs. *See* 54 Fed. Reg. 40286 (Sept. 29, 1989); *see also* 42 C.F.R. §§ 412.2(f)(7), 419.2(c)(1). These costs are reimbursed through payments made in settlement of the hospitals' annual Medicare cost reports, and are calculated in terms of the number of residents in approved GME programs at each hospital. *See* 42 U.S.C. § 1395ww(h).<sup>2</sup>

Physician direct patient care services that are covered by Medicare are reimbursed, instead, to the physician on a per claim basis under the Medicare physician fee schedule. *See* 42 U.S.C. § 1395w-4(a); 42 C.F.R. § 414.21. Accordingly, Medicare must distinguish between (i) direct patient care by a physician ("professional services"), payable to the physician under the fee schedule, and (ii) physician supervision of direct patient care by a resident (for which a hospital is reimbursed via the GME payments just discussed). If the physician is physically present during the "key" or critical portion of the service or procedure – *i.e.*, if the so-called Teaching Physician Rule (42 C.F.R. § 415.172(a)) is satisfied – then a physician claim for professional services is appropriate. If not, and the physician has done no more than supervise a

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<sup>2</sup> In addition to direct GME payments to hospitals, Medicare includes in hospital payments "indirect medical education" adjustments, to account for the higher costs associated with the enriched learning environment and steep learning curve that comes with resident involvement. These adjustments are also based on the number of residents in approved GME programs. *See* 54 Fed. Reg. 40286 (Sept. 29, 1989).

resident, then no separate physician bill is permitted because payment for such supervision is already factored into the calculation of the GME payment to the hospital.

Significantly, the Teaching Physician Rule does not speak to the level of *supervision* of residents that may be required in a hospital; it speaks only to whether the physician involvement constitutes a billable professional service *separate and apart* from any supervisory role he may have. Indeed, Medicare payment rules for inpatient hospital services are driven by the patient's diagnosis, and not by compliance with the Teaching Physician Rule (which does not apply to hospital services) or supervision of the inpatient services or the residents. 42 C.F.R. §§ 412.2(a), 412.60. In fact, Medicare has chosen not to impose explicit inpatient supervision requirements because of its view that hospitals have sufficient qualified practitioners available whenever inpatient hospital services are furnished. 74 Fed. Reg. 60316, 60582 (Nov. 20, 2009).

Similarly, Medicare's rules for coverage of outpatient hospital services, enumerated in 42 C.F.R. § 410.27, explicitly *reject* the physical presence requirement. Instead, they generally require "direct supervision," which "does not mean that the physician or nonphysician practitioner must be present in the room when [a] procedure is performed," but only that a supervising provider must be "immediately available to furnish assistance and direction throughout the performance of the procedure."<sup>3</sup> 42 C.F.R. § 410.27(a)(1)(iv)(A). And under many circumstances, a service may even be supervised by a non-physician such as a physician

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<sup>3</sup> Medicare may choose to designate a higher level ("personal supervision" – a supervisor must be in the room) or lower level ("general supervision" – the service need only be performed under the supervisor's overall direction and control) for particular outpatient hospital services; however, the program has not required personal supervision for *any* service, while determining general supervision to be sufficient for certain services, some of which constitute podiatric care. *See* 42 C.F.R. §§ 410.27(a)(1)(iv)(B), 410.32(b)(3)(i) & (iii); Centers for Medicare and Medicaid Services, Hospital Outpatient Therapeutic Services That Have Been Evaluated for a Change in Supervision Level (Mar. 10, 2015), <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Hospital-Outpatient-Therapeutic-Services.pdf> ("CMS Memo") (last visited June 8, 2016).

assistant, midwife, or nurse practitioner. 42 C.F.R. § 410.27(a)(1)(iv), (g).

## 2. Medicaid

Medicaid, established through Title XIX of the Social Security Act, 42 U.S.C. §§ 1396, *et seq.* (the “Medicaid Act”), provides federal funds to participating states to make medical care available to eligible indigent and low-income persons. The Department of Health (“DOH”) has been designated the “single State agency” responsible for administering the Medicaid program in New York State. 42 C.F.R. § 431.10(b)(1); N.Y. Pub. Health Law § 201(1)(v). As with Medicare, reimbursement to hospitals for Medicaid-covered services encompasses all of the functions that physicians provide, except for physicians’ professional services, for which physicians may bill and receive payment directly from Medicaid; physician services involving residents constitute billable professional services only if they satisfy the physical presence requirements of Medicaid’s virtually identical Teaching Physician Rule.<sup>4</sup>

Where Medicaid departs from Medicare is with respect to who qualifies as a “physician” for this purpose. Medicaid’s physical presence requirement for separate physician billing has *no application to podiatrists* in New York, given that federal Medicaid law does not define “physician” to include podiatrists, and New York distinguishes podiatrists from physicians, licensing them under different Articles of the Education Law. *See* 42 U.S.C. § 1396d(a)(5); N.Y. Educ. Law §§ 6521; 6522; 7001(1); 7002. Unlike *physician* professional services, *podiatrist* professional services are not separately covered services when provided in a hospital. Instead, all podiatrists’ services are “bundled” into the hospital rates: “The professional component for all other [(non-physician)] practitioners ... is included in the ... payment to the hospital ... [and such

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<sup>4</sup> *See* New York State DOH, Medicaid Update Vol. 25, No. 7 (June 2009), [https://www.health.ny.gov/health\\_care/medicaid/program/update/2009/2009-06.htm#sup](https://www.health.ny.gov/health_care/medicaid/program/update/2009/2009-06.htm#sup) (“June 2009 Medicaid Update”) (last visited June 8, 2016); New York State DOH, Medicaid Update Vol. 26, No. 4 (Mar. 2010), [https://www.health.ny.gov/health\\_care/medicaid/program/update/2010/2010-03.htm#fee](https://www.health.ny.gov/health_care/medicaid/program/update/2010/2010-03.htm#fee) (“March 2010 Medicaid Update”) (last visited June 8, 2016).

other] practitioners may not separately bill Medicaid for their professional services.” March 2010 Medicaid Update. In other words, hospitals may bill Medicaid for hospital services that include podiatry services, but podiatrists working in hospitals may not bill Medicaid for their professional services to patients. The Teaching Physician Rule is inapplicable and irrelevant.<sup>5</sup>

Also, as with Medicare, the Teaching Physician Rule directs when *separate payment* for physicians’ professional services is permitted; it says nothing about the level of supervision required for the inpatient or outpatient *hospital* service. And, although DOH has identified some basic parameters, it has largely deferred to each hospital’s discretion with respect to the creation of policies and procedures governing medical staff supervision of residents, and has focused on the duty of the medical staff to “monitor” and “supervise” residents on the whole. *See* 10 N.Y.C.R.R. § 405.4(f)(3). Consistent with this is DOH’s guidance on supervision and documentation for outpatient hospital billing, which acknowledges that “appropriate supervision” of residents and interns does not generally require that an attending physician be physically present when care is being given to a specific patient. June 2009 Medicaid Update.

#### **C. Relator’s Allegations**

The Amended Complaint purports to state three broad categories of allegations against all three Defendants.

##### **1. The Amended Complaint Alleges That Dr. Donovan Was Not Physically Present for Procedures Performed by Residents.**

The Amended Complaint alleges that Defendants improperly billed Medicare and Medicaid for Dr. Donovan’s professional services when those services were performed by

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<sup>5</sup> Discussions herein as to what *Medicaid* will reimburse refer to services that a provider might bill as Medicaid covered services. For patients that are Medicare/Medicaid dually eligible, services are billed to Medicare and reimbursed according to Medicare principles, even though such claims may be forwarded from Medicare to Medicaid to pay Medicare cost-sharing amounts otherwise due from the patient (*see* 42 U.S.C. §§ 1396a(a)(10)(E), 1396d(p)(3), 1396a(n); N.Y. Soc. Serv. Law § 367-a(1)(d), (g)).

residents and Dr. Donovan was not physically present, thereby violating the Teaching Physician Rule. Am. Cplt. ¶¶ 46-64. Relator identifies a single date, May 11, 2012, on which Dr. Donovan allegedly attended a conference off-site while Relator and another resident treated seven patients in the CIH clinic. Am. Cplt. ¶ 50. Relator alleges that “Defendants” billed “the Federal Health Programs” (Medicare and Medicaid) under Defendants’ SOP’s, but does not identify whether those bills reflected the provision of specific services by specific types of providers, or what those SOPs say or to whom they apply. Am. Cplt. ¶ 52. The Amended Complaint also alleges that Dr. Donovan “seldom attends” inpatient or emergency room care, but that “Defendants have billed and continue to bill the Federal Health Care Programs for Donovan’s services as if he had personal involvement in the treatment rendered.” *See* Am. Cplt. ¶¶ 58, 63. The Amended Complaint does not provide examples of any bills resulting from such alleged conduct.

**2. The Amended Complaint Alleges That Certain PMSR Residents Did Not Hold LRPs as Required by New York State Education Law.**

Relator alleges that two of her fellow PMSR program residents did not obtain, or failed to renew, an LRP required by New York Education Law § 7008 specifically for podiatry residents in hospital settings. Am. Cplt. ¶¶ 65-68, 72. Relator identifies several procedures performed on patients in which one or both of these residents “assisted,” but does not identify whether any of these patients were Medicare or Medicaid participants. Am. Cplt. ¶¶ 70, 75. Relator alleges that Defendants’ receipt of payments related to their participation in the PMSR program, and their assistance in treating patients, violated 42 C.F.R. § 413.75(b). Relator also again alleges that Defendants submitted inappropriate charges to both Medicaid and Medicare for the services of these residents, but fails to identify any such bills. Am. Cplt. ¶¶ 71, 76.

**3. The Amended Complaint Alleges That Defendants Misled the CPME to Maintain Approval of the PMSR Program and Obtain GME Funding.**

The Amended Complaint states that “[h]ospitals must have approved graduate medical education programs to qualify for [GME] payments” and, in the field of podiatry, “an ‘approved’ program is a residency program approved by the [CPME].” Am. Cplt. ¶ 42.

The Amended Complaint acknowledges that the PMSR program was approved by the CPME at all relevant times, and remains so. However, the Amended Complaint claims that violations of CPME standards (Am. Cplt. ¶¶ 77-97) somehow transformed the program to non-approved status “for purposes of Medicare and Medicaid reimbursement.” Am. Cplt. ¶ 95. Relator speculates that the PMSR program would not have maintained approval if the CPME knew of its compliance issues (*id.*), but alleges at the same time that Relator alerted the CPME of the very “core deficiencies” of which she complains. Yet, the CPME performed a review and still approved the PMSR program. Am. Cplt. ¶ 96. Nevertheless, Relator alleges that “[e]very annual cost report filed by CIH from in or about 2006 through at least in or about 2014” without disclosing “the fraud infecting the Program, or the fact that CIH was dishonestly maintaining the Program’s ‘approved’ status, constituted a false claim for GME funding.” Am. Cplt. ¶ 97. The Amended Complaint does not, however, provide any examples of any such cost report.

For the reasons stated below, Relator’s Amended Complaint should be dismissed.

**FALSE CLAIMS ACT STANDARDS OF REVIEW**

The FCA prohibits “knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval” to the United States Government, or conspiring to do so. 31 U.S.C. § 3729. The “knowledge” must be (a) actual knowledge, (b) deliberate ignorance, or (c) reckless disregard of the truth or falsity of the alleged false claims. 31 U.S.C.

§ 3729(b)(1)(A).<sup>6</sup> An FCA complaint can be based on the theory that a claim was factually false, where goods or services are described as something they are not, or where a request is made “for reimbursement for good[s] or services never provided,” *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001). FCA complaints can also be based on a theory that claims were legally false, “predicated upon a false representation of compliance with a federal statute or regulation or a prescribed contractual term.” *Id.* at 696. For a claim to be legally false, it must be predicated on either an express or an implied certification.

An express false certification would be “a claim that falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment.” *Id.* at 698. A complaint alleging this theory “cannot be premised on anything as broad and vague as a certification that there has been compliance with ‘all federal, state and local statutes, regulations [and] policies.’” *United States ex rel. Feldman v. City of New York*, 808 F. Supp. 2d 641, 652 (S.D.N.Y. 2011); *see also Mikes*, 274 F.3d at 698 (for an express false certification, plaintiff must allege that the defendant submitted “a claim that falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment”); *Bishop v. Wells Fargo & Co.*, 823 F.3d 35, 41-42 (2d. Cir. 2016) (an express false certification cannot be premised on a certification that defendant is “not in violation of any laws or regulations”); *United States ex. rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 714 (6th Cir. 2013) (reliance on a provision to “abide by the Medicare laws, regulations and program instructions ... as an express certification violating the FCA is misplaced.”).

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<sup>6</sup> The language of the NYFCA “mirrors that of its federal analogue” in most respects. *United States v. Icahn Sch. of Med. at Mount Sinai*, No. 12 Civ. 5089(GBD), 2015 WL 5472933, at \*7 (S.D.N.Y. Sept. 16, 2015). The same pleading standards apply. *United States ex. rel. Mooney v. Americare, Inc.*, No. 06-CV-1806(FB)(VVP), 2013 WL 1346022 at \*2 (E.D.N.Y. April 3, 2013). Accordingly, references to the “FCA” include the NYFCA, and the arguments herein apply to both, unless otherwise noted.

The implied certification theory can be a basis for liability “where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant’s failure to disclose non-compliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.” *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016). The requirement that specific goods or services must be identified determines the scope of the representations implicitly made: submitting the claims impliedly represents compliance with those requirements that are material to payment for those services; non-compliance renders those implicit representations false.

Under the FCA, “the misrepresentation must be *material to the other party’s course of action.*” *Id.* at 2001 (emphasis added). The Supreme Court described the materiality requirement as “rigorous” and “demanding,” explaining that plaintiffs must plead facts with particularity “to support allegations of materiality.” *Id.* at 2003, 2004 n.6. Whether or not the Government has designated a regulatory requirement as an express condition of payment “is relevant to but not dispositive of the materiality inquiry.” *Id.* at 2001. Further, “if the Government pays a particular claim [or . . .] regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated . . . that is strong evidence that the requirements are not material.” *Id.* at 2003-04. The materiality requirement “look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.” *Id.* at 2002. It is not sufficient “that the Government would have the option to decline to pay if it knew of the defendant’s noncompliance [or] where noncompliance is minor or insubstantial.” *Id.* at 2003.

A Complaint must be dismissed under Rule 12(b)(6) if it fails to state a claim for relief that is “plausible on its face.” *Law Practice Mgmt. Consultants, LLC v. M&A Counselors &*

*Fiduciaries, LLC*, 599 F. Supp. 2d 355, 358 (E.D.N.Y. 2009) (Spatt, J.) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007)). To survive a motion to dismiss, such claim must be above “the speculative level,” *Twombly*, 550 U.S. at 555, and must “allege facts that are not merely consistent with the conclusion that the defendant violated the law, but which actively and plausibly suggest that conclusion.” *Law Practice Mgmt. Consultants*, 599 F. Supp. 2d at 358 (citations omitted). “Even assuming [an FCA complaint’s] accusations of widespread fraud are true,” a relator must “plausibly connect[] those accusations to express or implied false claims submitted to the government for payment, as required to collect the treble damages and other statutory penalties available under the FCA.” *Bishop*, 823 F.3d at 39. Therefore, to make out a claim under the FCA, Relator must plausibly allege that (i) claims for payment have been submitted to the government; (ii) those claims represent that specific services were provided and identify the provider of those services; (iii) there were certain obligations, compliance with which was required with respect to such services; and (iv) such compliance was lacking even though compliance was material to the government’s payment of the claims.

In addition, FCA complaints fall within the scope of Rule 9(b), which requires that plaintiffs “state with particularity the specific statements or conduct giving rise to the fraud claim.” *Wood ex. rel. United States v. Applied Research Assocs., Inc.*, 328 F. App’x. 744, 747 (2d Cir. 2009); *see also United States ex rel. Smith v. New York Presbyterian Hosp.*, No. 06 Civ. 4056(NRB), 2007 WL 2142312 at \*6 (S.D.N.Y. 2007). Rule 9(b) is not merely formalistic; it “serves to provide a defendant with fair notice of a plaintiff’s claim, to safeguard a defendant’s reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit,” *Rombach v. Chang*, 355 F. 3d 164, 171 (2d Cir. 2004) (internal quotation marks omitted), as well as “to discourage fishing expeditions.” *Americare, Inc.*, 2013

WL 1346022, at \*7. Pleadings subject to Rule 9(b) must “(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state *where* and *when* the statements were made, and (4) explain *why* the statement was fraudulent.” *Bishop*, 823 F.3d at 43.<sup>7</sup>

### ARGUMENT

#### **I. THE AMENDED COMPLAINT SHOULD BE DISMISSED BECAUSE IT FAILS TO PLEAD FRAUD WITH THE PARTICULARITY REQUIRED BY RULE 9(b).**

The Amended Complaint fails to satisfy the heightened pleading threshold applicable to claims of fraud under Rule 9(b): to state “with particularity the circumstances constituting fraud.” *See Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1477 (2d Cir. 1995) (per curiam). As discussed more fully below, the Amended Complaint fails to specify (1) any particular bills Relator claims were false or fraudulent, (2) who submitted them, (3) where they were submitted, (4) to whom they were submitted, and (5) what made them false or fraudulent. *See Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993); *see also United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704(ERK), 2009 WL 1456582, at \*4 (E.D.N.Y. May 22, 2009). Nor does the Amended Complaint allege facts raising at least a strong inference of scienter by each Defendant, as Rule 9(b) requires. *See United States ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d 313, 326 (S.D.N.Y. 2004).

In *Universal Health*, the Supreme Court raised the importance of the particularity requirement applicable to FCA pleadings, by limiting FCA liability to situations in which the claims for payment themselves identify the specific goods and services for which payment is requested. The Court explained that an FCA claim cannot stand if it “merely request[s] payment.” Rather, the Court assigned critical importance to allegations that the defendants in

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<sup>7</sup> Emphasis is added unless stated otherwise.

that case had “made representations about the specific services provided by specific types of professionals,” “using payment codes that correspond to specific counseling services,” and provider numbers “corresponding to specific job titles.” *Id.* at 1998, 2000. The Court reasoned that by submitting claims so identified, the defendant represented implicitly that it had complied with conditions material to government payment for those specific treatments. *Id.* at 2000-01.

The detailed allegations that the Court considered so important in *Universal Health* – that the defendants did not merely request payment, but made specific representations that were rendered false by material omissions – are absent from the Amended Complaint here. In fact, the absence of such allegations not only renders the pleadings defective under Rule 9(b), as there is no indication of who made what representations to which payer under what circumstances that would allegedly render them false; it causes Relator’s allegations to fail to state a claim under Rule 12(b)(6), which requires that bills for specific services must be identified in order for the Court to infer what implicit representations as to compliance, and omissions as to non-compliance, were made, and whether they were material, as required for FCA liability to attach.<sup>8</sup>

**A. The Amended Complaint Fails To Plead With Particularity *What Allegedly False Claims Were Made.***

The Amended Complaint does not identify a single bill, let alone specify the particulars of such a bill, submitted to Medicare or Medicaid by any Defendant. “The FCA attaches liability, not to the underlying fraudulent activity or to the government’s wrongful payment, but to the

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<sup>8</sup> The Supreme Court highlighted this nexus between satisfaction of Rules 9(b) and 12(b)(6) with respect to FCA claims, in the context of the materiality requirement announced in *Universal Health*. The Court “reject[ed] *Universal Health*’s assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment,” recognizing that the bar that plaintiffs must meet to plead an FCA claim with particularity under Rule 9(b) is a “familiar and rigorous one” that requires plaintiffs, in any event, to “plead[] facts to support allegations of materiality.” *Universal Health*, 136 S. Ct. at 2004 n.6. As the materiality of the alleged implicit misrepresentation is essential to FCA liability, failure to plead with particularity facts that would demonstrate a material misrepresentation creates a failure, as well, to state a claim for FCA liability under Rule 12(b)(6).

‘claim for payment’ … [t]hus, the *submission* of a false claim is the ‘*sine qua non*’ of a False Claims Act violation.” *United States ex. rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 253 (S.D.N.Y. 2014). Accordingly, the FCA “does not create liability merely for a health care provider’s disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe.” *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002); *see also United States ex. rel. Moore v. GlaxoSmithKline, LLC*, No. 06 Civ. 6047(BMC), 2013 WL 6085125, at \*5 (E.D.N.Y. Oct. 18, 2013) (Cogan, J.) (“Unless a false claim is actually presented to the government, even where the practices of an entity that provides services to the Government may be unwise or improper, there is simply no actionable damage to the public fisc as required under the False Claims Act.”).

Because the FCA creates liability only for the wrongful *submission of claims* to the federal government, a relator must “allege the particulars of the false claims *themselves*.” *See, e.g., United States ex. rel. Corporate Compliance Associates v. N.Y. Soc'y for the Relief of the Ruptured and Crippled, Maintaining the Hosp. for Special Surgery*, No. 07 Civ. 292(PKC), 2014 WL 3905742, at \*12 (S.D.N.Y. Aug. 7, 2014). It is insufficient under Rule 9(b) for a relator to plead a course of conduct that could potentially have, but also could potentially not have, led to a false bill for payment being submitted to the state or federal government. *See Pfizer, Inc.*, 2009 WL 1456582, at \*5 (“[A] relator cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in detail and concluding that as a result of the fraudulent scheme, false claims must have been submitted.”); *Kester*, 23 F. Supp. 3d at 253 (same); *United States ex. rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 457 (4th Cir. 2013) (“[W]hen a defendant’s actions … could have led, but need not necessarily have led, to the submission of

false claims, a relator must allege with particularity that specific false claims *actually* were presented to the government for payment.”).

Here, no inference can be drawn from the Amended Complaint to conclude that any Defendant knowingly submitted false bills, or caused them to be submitted. Relator in two successive complaints has not alleged the details or provided a single false bill that was submitted for payment. This court and courts in this Circuit have routinely dismissed such complaints as deficient, particularly in the healthcare context.<sup>9</sup>

Indeed, the Courts have dismissed virtually identical claims by disgruntled former doctors and residents who allegedly witnessed violations of regulations requiring the presence or supervision of a teaching physician in order to bill for services performed by residents, but provided no particulars identifying actual bills submitted for such procedures. Where a former radiologist brought suit under the FCA against Yale University for submitting claims for physician services based on studies performed by radiology residents without the presence or supervision of the teaching physician, the court held, in addition to dismissing the complaint on other grounds, that it was not pleaded with sufficient particularity to satisfy Rule 9(b) because “Relator fail[ed] to identify a single false or fraudulent bill submitted to the federal government,” *Yale Univ.*, 415 F. Supp. 2d at 84, and failed to identify “a specific amount of charges that were submitted, provide[] dates that false claims were submitted or provide[] a copy of a single bill or payment.” *Id.* at 87.

Similarly, in *Johnson*, former anesthesiology residents alleged that the University of

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<sup>9</sup> See, e.g., *GlaxoSmithKline, LLC*, 2013 WL 6085125, at \*5; *United States ex rel. Siegel v. Roche Diagnostics, Corp.*, 988 F. Supp. 2d 341, 346 (E.D.N.Y. 2013); *Pfizer, Inc.*, 2009 WL 1456582, at \*4; *Americare, Inc.*, 2013 WL 1346022, at \*6; *United States ex. rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 84 (D. Conn. 2006); *Johnson v. Univ. of Rochester Med. Ctr.*, 686 F. Supp. 2d 259, 267 (W.D.N.Y. 2010); *Icahn Sch. of Med. at Mount Sinai*, 2015 WL 5472933, at \*5; *United States ex rel. NPT Assocs. v. Lab. Corp. of Am. Holdings*, No. 1:07-cv-05696, 2015 WL 7292774, at \*6 (S.D.N.Y. Nov. 17, 2015); *Corporate Compliance Assocs.*, 2014 WL 3905742, at \*17.

Rochester violated the FCA by billing Medicare or Medicaid for procedures they had performed without the physical presence of a teaching physician. *Johnson*, 686 F. Supp. 2d at 265-67. The Court dismissed the claims for failing to allege sufficient particulars about any actual bills submitted for payment, finding that “[n]owhere in their lengthy pleading do the plaintiffs allege or describe how, *or even if*, any bills for procedures involving falsified records were ever presented to Medicare or Medicaid for payment” and holding therefore that “the plaintiffs’ fraud claims do not state a claim, but merely speculate that a claim might exist.” *Id.*

Here, the original complaint alleged false billing based on Relator’s “information and belief.”<sup>10</sup> The Amended Complaint removed those references, and substituted allegations that Medicare and Medicaid were billed under “Defendants’ SOP’s.” *Compare* Original Complaint ¶ 47, 50, 53 *with* Am. Cplt. ¶ 52, 57, 62. The Amended Complaint, however, provides no detail in support of these conclusory allegations, does not identify whose procedures these are, what these procedures are, or how or why they led some unspecified combination of NYC Health + Hospitals, PAGNY, and Dr. Donovan, to submit claims for payment that were not eligible for reimbursement. As explained above, *see* pp. 6-10, *supra*, there are different rules and reimbursement practices for professional billing, hospital services billing, and GME funding, and the notion that three disparate Defendants – an individual podiatrist, a public benefit organization and a private company – knowingly designed and implemented SOPs to allow fraudulent billing is simply not plausible in the absence of any further explanation. And bald allegations of SOPs do not even constitute allegations that billing, in fact, occurred. Most institutions follow certain

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<sup>10</sup> Relator’s alleged “information and belief” at that time purported to include CIH, which has no corporate existence separate from NYC Health + Hospitals, but not PAGNY, which was added as a Defendant in the Amended Complaint, albeit without any specific factual allegations against it. In any event, “information and belief” is inadequate to satisfy Rule 9(b) unless accompanied by particularized facts upon which the belief is based. *See Corporate Compliance Assocs.*, 2014 WL 3905742, at \*22 (*citing First Capital Asset Mgmt., Inc. v. Satinwood, Inc.*, 385 F.3d 159, 179 (2d Cir. 2004)).

standard procedures in the ordinary course of their affairs, but to allege that they do so, without explaining anything in particular about what those procedures say or how they work, and without identifying any claim submitted as a result of them, is tantamount to alleging *nothing* indicative of false or fraudulent claims.

Courts in this Circuit have rejected the argument that a relator may “make fairly conclusory allegations that claims were submitted for medical services pursuant to a standard billing practice.” *Kester*, 23 F. Supp. 3d at 255. The court in *Kester* explained:

A complaint’s description of a fraudulent scheme paired with information about a defendant’s standard billing practice is not enough ‘particular’ information to fulfill the purposes of Rule 9(b); the plaintiff must provide a detailed factual basis to support his allegations that the defendant submitted a false claim *in this specific instance*, not just that the defendant had a custom of submitting false claims.

*Id.* (emphasis in original). Likewise, the *Yale Univ.* court expressly rejected as insufficient and “lacking factual substantiation” relator’s claims that “Yale has a long-standard practice of billing the Professional Component of Radiology Services for all reports that are signed,” and explained that the “policy of not subjecting a defendant to the time and expense of defending an ‘improvident’ claim requires evidence of some ... instance of actual billing to sufficiently allege that fraud occurred.” *Yale Univ.*, 415 F. Supp. 2d at 87.

**B. The Amended Complaint Fails to Plead with Particularity *Who* Knowingly Submitted *What* Claims for Payment.**

**1. Impermissible Blanket Allegations Are Asserted Against All Defendants.**

The Amended Complaint fails to distinguish among the three Defendants’ roles in the alleged fraudulent billing conduct. Even assuming, *arguendo*, there were false bills, there is simply no way to discern from the allegations which of the Defendants submitted false bills, or caused false bills to be submitted, or for which services. Am. Cplt. ¶ 53, 58, 63. While the Amended Complaint makes numerous allegations to the effect that Dr. Donovan was absent

during procedures, it says nothing about any specific billing in which he allegedly engaged, and nothing with respect to the alleged participation of PAGNY and NYC Health + Hospitals. The importance of particularity in this context is critical, however; as discussed above (pp. 7-11), billing practices and reimbursement requirements differ significantly for hospital services, for physician professional services, and for GME payments, and they also differ for Medicare and Medicaid. See also, pp. 33-37, *infra*.

“Where multiple defendants are asked to respond to allegations of fraud, the complaint should inform each defendant of the nature of his alleged participation in the fraud.” *DiVittoria v. Equidyne Extractive Indus., Inc.*, 822 F.2d 1242, 1247 (2d Cir. 1987). Where a complaint makes “blanket allegations concerning the alleged misconduct” of all the defendants, including both doctors and a hospital, it “fail[s] to satisfy Rule 9(b).” *Corporate Compliance Assocs.*, 2014 WL 3905742, at \*19-20 (dismissing complaint under Rule 9(b), which alleged “[a]ll nine causes of action ... against all three ... ‘Defendants,’ collectively” and that all “three defendants [were] liable on each count, even where the substantive allegations claim wrongdoing solely by the Hospital,” and “fail[ed] to distinguish between the defendants’ roles in the various alleged schemes.”); *see also United States v. Corinthian Colls.*, 655 F.3d 984, 997-98 (9th Cir. 2011); *DiVittoria*, 822 F.2d at 1247; *Mills*, 12 F.3d at 1175 (“Rule 9(b) is not satisfied where the complaint vaguely attributes the alleged fraudulent statements to ‘defendants.’”); *Ritani, LLC v. Aghjayan*, 970 F. Supp. 2d 232, 250 (S.D.N.Y. 2013) (“Rule 9(b) is not satisfied by a complaint in which defendants are clumped together in vague allegations.”).<sup>11</sup>

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<sup>11</sup> The Amended Complaint also fails to plead the particulars of any agreement that could constitute an FCA conspiracy, and therefore those claims must also be dismissed. *See, e.g., Corporate Compliance Assocs.*, 2014 WL 3905742, at \*25 (FCA conspiracy was not pleaded with particularity because complaint did not identify roles of defendants in the conspiracy, the nature of the conspiracy itself, or when the conspiracy began); *United States ex rel. Assocs. Against Outlier Fraud v. Huron Consulting Grp., Inc.*, No. 09 Civ. 1800(JSR), 2010 WL 3467054, at \*3 (S.D.N.Y. Aug. 25, 2010) (FCA conspiracy was not

**2. The Amended Complaint Fails to Plead with Particularity *In What Way* Any Claims Were False or Fraudulent.**

The Amended Complaint fails to link, as it must, each Defendant's actions with a violation of a particular section of the FCA. Sections I-IV of the Amended Complaint list various statutes, regulations, billing manuals, and form certifications that are supposedly applicable to Defendants; Section V describes Defendants' alleged conduct without citing which of these rules each Defendant allegedly violated, or by which form each Defendant certified compliance; Section VI makes the blanket allegation that "Defendants" are liable under four different causes of action under the FCA, and four additional causes of action under the NYFCA, without specific reference to any of the laws in Sections I-IV or facts in Section V. Indeed, the first count merely alleges that "By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States government for payment or approval." Am. Cplt. ¶ 109. The other counts make similar vague and conclusory statements. Am. Cplt. ¶¶ 115, 121, 127, 132, 138, 144, 150.

Such pleading fails to identify which of the first 106 paragraphs of the Amended Complaint are alleged to give rise to liability for each particular Defendant under each particular count. The Amended Complaint fails to put each Defendant on notice as to which of its/his own acts or representations are alleged to have violated which provision of the law. Such conclusory pleading fails to meet Rule 9(b)'s particularity requirement regarding *the way in which* the claims supposedly submitted by each defendant violated particular sections of the FCA.

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pledged with particularity because plaintiff failed to particularize "the conspirators' conscious agreement to undertake the conspiracy.").

**II. THE COURT SHOULD DISMISS THE AMENDED COMPLAINT PURSUANT TO RULE 12(b)(6) FOR FAILING TO STATE AN FCA CLAIM THAT IS PLAUSIBLE ON ITS FACE.**

The Amended Complaint identifies certifications included on Medicare and/or Medicaid claim forms that broadly state they are “accurate, complete and truthful,” or words to that effect (Am. Cplt. ¶¶ 24, 26, 41), but it neither ties those statements to any specific allegations about Defendants nor specifies what makes them false. Relator also references such generic certifications as “all care and services were rendered in compliance with federal and state laws and regulations, as well as all DOH policies,” or “the services identified in [the] cost report were provided in compliance with ... laws and regulations” regarding the provision of healthcare services. Am. Cplt. ¶¶ 26, 41, 67. Such blanket certifications are much too broad and generic to be the basis for an express false certification claim. *See* pp. 12-16, *supra*, and cases cited therein. Accordingly, the Amended Complaint must necessarily rely on a theory of implied certification which, in order to be actionable in this case, requires allegations of (i) a representation that specific services were provided (from which an implicit representation of compliance with certain pre-conditions of payment for those services is inferred) and (ii) non-compliance with a material precondition of payment for such services (creating a misrepresentation by omission that is material to the government’s decision to pay). *Universal Health*, 136 S. Ct. at 2001.

As discussed below, Relator fails to allege facts that would plausibly support an inference that Medicare or Medicaid would *not* have reimbursed claims for *hospital* services, had they been submitted; therefore, as to Defendant NYC Health + Hospitals, the Amended Complaint must be dismissed under Rule 12(b)(6) in its entirety. While a claim against Dr. Donovan could theoretically be possible – with respect to billing for his professional services to the Medicare program only – the Amended Compliant fails to identify any Medicare claim actually submitted for such a service. And with respect to PAGNY, there are no factual allegations at all, let alone

any sufficient to plead a claim of fraudulent billing for a podiatrist's professional services.

**A. The Allegations Concerning Improper Medicare and Medicaid Billing for Hospital and Podiatrists' Professional Services Should Be Dismissed.**

The Amended Complaint conflates and confuses different billing practices and concepts. Its allegations concerning billing for hospital and professional services are premised upon a fundamental misunderstanding of the legal framework and applicable laws that govern Medicare and Medicaid billing by hospitals and practitioners. Relator alleges that billing for hospital and professional services in instances in which residents furnished care and Dr. Donovan was not physically present necessarily (i) would have been inappropriate and the bills therefore would be false, and (ii) must have occurred. In fact, both of these allegations are insufficient and/or implausible, and fail to state a claim for relief under Rule 12(b)(6).

**1. The Allegations Concerning Billing for Hospital Services Incorrectly State That Dr. Donovan's Physical Presence Was Required.**

Relator's claim that hospital bills were submitted for "unsupervised" podiatric residents' services (see Am. Cplt. ¶¶ 53, 58, 63) is predicated on the false notions that the presence of Dr. Donovan himself (and no other doctor) (i) was in fact, legally required, and (ii) was material to Medicare or Medicaid payment for hospital services. Medicare and Medicaid, however, *do not require* that any one particular physician be physically present in order for the hospital to receive payment for hospital services, whether inpatient, outpatient or emergency room. Accordingly, bills for such hospital services would not be "legally false" even if Dr. Donovan was absent.

Relator's allegations concerning hospital billing rely primarily on the Teaching Physician Rule (under Medicare and its Medicaid analog) but, as noted (*supra* at pp. 8-9), that Rule governs billing for *physician professional services*, and does not apply to hospital services at all. See 42 C.F.R. § 415.172(a) ("[i]f a resident participates in a service furnished in a teaching setting, *physician fee schedule payment* is made only if a teaching physician is present during the

key portion of any service or procedure for which payment is sought”); *United States ex. rel. Goldberg v. Rush Univ. Med. Ctr.*, 929 F. Supp. 2d 807, 824 (N.D. Ill. 2013) (“The Teaching Physician Rule … has no application to facility fee payments to hospitals.”). The Teaching Physician Rule is not about physician *supervision* of residents; rather, its goal is to ensure that physicians who bill for their professional services were physically present during a critical portion of the service so as to justify a *professional service* bill separate from the bill for hospital services (*supra* at pp. 8-9). As Relator has offered no other valid basis from which to conclude hospital billing was improper, she has alleged nothing that would constitute non-compliance with a condition of payment – material or otherwise – for hospital services, and thus, has alleged no basis for inferring any false representations of compliance. Accordingly, her claims against NYC Health + Hospitals and PAGNY must be dismissed under Rule 12(b)(6).

**a. Dr. Donovan’s Physical Presence and Supervision Was Not Required Under Medicare Outpatient Hospital Billing Rules.**

The Amended Complaint cites no authority to support its allegations of improper *Medicare outpatient* hospital billing. To the contrary, Medicare has made clear that its “direct supervision” standard does not require a supervising practitioner to be in the room at the time a service is furnished. *See* 42 C.F.R. § 410.27(a)(1)(iv)(A). This Regulation requires supervision of hospital outpatient services *generally* – it does not relate specifically to residents’ activities – and requires at most that *some qualified practitioner* (not necessarily the residency Program Director or even a physician<sup>12</sup>) be “immediately available to furnish assistance and direction throughout the performance of the procedure.” Crucially, Relator’s Amended Complaint fails to allege that there were *no qualified supervising practitioners sufficiently available* when outpatient services

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<sup>12</sup> 42 C.F.R. § 410.27(g) defines “nonphysician practitioner” as “a clinical psychologist, licensed clinical social worker, physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse-midwife.”

were provided; it alleges only that *Dr. Donovan* was not present, in the room, which, even if true, fails to state a claim that the applicable Medicare supervision standard was violated.

**b. Dr. Donovan's Physical Presence and Supervision Was Not Required Under *Medicaid Outpatient* Hospital Billing Rules.**

As for *Medicaid outpatient* hospital services, Relator cites a Medicaid Update from June 2009 (see Am. Cplt. ¶ 37), which addresses supervising/teaching physician documentation in the clinic setting, and advises that residents “should only provide medical care under appropriate supervision.” However, DOH acknowledges in that Update that “appropriate supervision” of residents does not generally require that an attending physician be physically present when care is being given to a specific patient. Therefore, merely alleging the absence of Dr. Donovan cannot possibly support a claim that billing for hospital services violated Medicaid requirements.

**c. Dr. Donovan's Physical Presence and Supervision Was Not Required Under *Medicare Inpatient* Hospital Billing Rules.**

Relator has alleged no Medicare authority that requires physician supervision of residents in connection with inpatient hospital services, let alone any that are material to inpatient hospital payments. To the contrary, the federal Medicare agency has announced that it has “not established explicit [inpatient] supervision requirements in regulations because [the federal government] believe[s] hospitals would have physicians or other qualified practitioners available at all times that complex hospital inpatient services are being furnished.” 74 Fed. Reg. 60316, 60582. Accordingly, Relator’s allegations of improper inpatient hospital billing of Medicare are simply wrong. No particular level of supervision is required, so no particular level of supervision is implicitly represented by the associated hospital bill; thus, no facts tending to state a claim for FCA liability have been alleged in this context. *Universal Health*, 136 S. Ct. at 2001 (holding that the implied certification theory is a basis of liability where, unlike here, “the defendant’s failure to disclose noncompliance with material statutory, regulatory, or contractual requirements

makes those representations misleading half-truths.”).<sup>13</sup>

**d. Dr. Donovan’s Physical Presence and Supervision Were Not Required Under Medicaid Inpatient Hospital Billing Rules.**

Relator also cites to Medicaid Inpatient Manual Policy Guidelines, which she alleges identify supervision requirements for attending physicians as a condition for Medicaid inpatient hospital payment. *See Am. Cplt. ¶ 36.* However, this section of the Policy Manual does no more than present a set of services that “must be given by the attending physician or the resident with oversight by the attending physician” *at some point* during a Medicaid patient’s inpatient stay (*which, of course, might span multiple days*). New York State Medicaid Program Inpatient Manual Policy Guidelines (Nov. 21, 2012), [https://www.emedny.org/ProviderManuals/Inpatient/PDFS/Inpatient\\_Policy\\_Guidelines.pdf](https://www.emedny.org/ProviderManuals/Inpatient/PDFS/Inpatient_Policy_Guidelines.pdf) at 10 (last visited June 8, 2016). The Amended Complaint does not allege that Dr. Donovan, or any other doctor, failed to provide the “personal and identified services” specified in the Manual over the course of any particular inpatient stay.

While the Manual does require that “[s]urgical residents ... have personal supervision by the attending physician,” the Amended Complaint does not allege that residents performed surgeries without an “attending physician” present to personally supervise them. Relator’s allegations that *Dr. Donovan* “seldom attends” or “has any personal role” in “visits” that might include surgical procedures are irrelevant; there is no allegation that that there were *no physicians* present during specific surgical procedures. *See Am. Cplt. ¶¶ 48, 56, 61.* In fact, among the few paragraphs in which the Amended Complaint refers to specific dates, it identifies surgeries on which the residents “assisted,” implying that someone other than the resident

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<sup>13</sup> The Amended Complaint cites only Medicare regulations 42 C.F.R. §§ 409.10(a)(7) and 409.15(c) for the allegation that “medical or surgical services furnished by residents are included by Medicare as inpatient hospital services if they are provided by the resident under an approved teaching program.” Am. Cplt. ¶ 35. But those regulations simply *confirm* that residents’ services are encompassed by inpatient hospital services without regard to anything except the approved status of their teaching program.

performed the surgery. *See* Am. Cplt. ¶¶ 70, 75.

**2. Relator's Allegations Concerning Billing for *Professional Services* Are Implausible and Not Pled with Sufficient Particularity.**

Relator's primary authority in support of her claim that there was improper billing for inadequately supervised resident services when Dr. Donovan was absent is the physical presence requirement of the Teaching Physician Rule, 42 C.F.R. § 415.172, and its Medicaid analog. With respect to Medicaid coverage, this argument fails because a *podiatrist*'s professional service furnished in a hospital is simply not a Medicaid covered service that is payable separate and apart from the hospital service. Medicare, on the other hand, would, indeed, apply the Teaching Physician Rule as a condition of payment with respect to claims for podiatrist professional services; however, the Amended Complaint has not identified a single Medicare claim for professional services submitted by any Defendant.

**a. Medicaid Does Not Independently Reimburse Dr. Donovan's Professional Services.**

Defendants do not dispute that the New York State Medicaid Program Physician Manual, cited by Relator (Am. Cplt. ¶ 34), generally provides that doctors of medicine or osteopathy supervising residents may bill Medicaid only if "personal and identifiable" services are provided by such physician. However, the Manual applies to "doctors o[f] medicine and osteopathy licensed under Article 131 of the New York Education Law," Am. Cplt. ¶ 34. Doctors of podiatric medicine are licensed under Article 141 of the N.Y. Education Law, as acknowledged in the Amended Complaint. Am. Cplt. ¶ 33; N.Y. Educ. Law §§ 7000, *et seq.*

In New York, Medicaid payment for professional services of podiatrists in hospitals is bundled into the Medicaid payment for hospital services; no payment for podiatry professional services is available, separate and apart from the hospital payment. Accordingly, the physical presence rules, which are a pre-condition to billing for *physician* professional services furnished

in a hospital when residents are involved, do not apply.<sup>14</sup>

**b. The Amended Complaint Does Not Identify Any Medicare Patients Treated or Bills Submitted by Defendants.**

Although professional services may be billed to *Medicare* by podiatrists in a hospital setting, provided that the Teaching Physician Rule is satisfied where residents are involved in such care, the Amended Complaint does not identify a single treated Medicare patient. *See United States ex. rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 35 (D.D.C. 2003) (dismissing FCA claims where the “allegations are not connected specifically to Medicare patients”). Even with respect to May 11, 2012, as to which Relator alleges that she and another resident treated seven patients at CIH while Dr. Donovan and others attended a conference off-site, the Amended Complaint alleges that six of the patients “were covered by Medicaid,” and is silent about Medicare. Am. Cplt. ¶ 50. Relator has not alleged that Dr. Donovan or any other party<sup>15</sup> submitted bills to Medicare for such services.

**c. Relator Does Not Describe Any False Statements from Dr. Donovan That He Was Physically Present When He Was Not.**

Relator asserts that Dr. Donovan “falsely indicate[d] that he was present for ... patient encounter[s]” in his notes related to the seven patients treated when he was at a conference on May 11, 2012. *See* Am. Cplt. ¶¶ 50, 51. With respect to the six Medicaid patients, there would have been no point to such subterfuge, as professional podiatrist services are not separately billable to Medicaid, and hospital services are billable without regard to Dr. Donovan’s presence.

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<sup>14</sup> *See* March 2010 Medicaid Update (health practitioners other than physicians may not bill separately for Medicaid professional services); DOH Policy And Billing Guidance Ambulatory Patient Groups (APGs) Provider Manual, Rev. 2.1, § 4.1 (Aug. 2012), [https://www.health.ny.gov/health\\_care/medicaid/rates/apg/docs/apg\\_provider\\_manual.pdf](https://www.health.ny.gov/health_care/medicaid/rates/apg/docs/apg_provider_manual.pdf) (last visited June 10, 2016) (“The services of other licensed practitioners (dentists ... podiatrists) ... are always included in the ... payment to the facility and may not be billed separately to Medicaid in the clinic or hospital ... setting.”).

<sup>15</sup> Relator has not alleged any assignment from Dr. Donovan to NYC Health + Hospitals or to PAGNY of his right to bill Medicare for his professional services; absent such assignment, neither Defendant could have submitted a bill to Medicare for such services. *See* 42 C.F.R. § 424.80.

Moreover, the two quoted notes – “the patient tolerated the visit well” and “tolerated LIDO/Steroid injection well for painful [heel]” – do not even purport to indicate Dr. Donovan’s physical presence. These notes are devoid of words such as “I,” “Dr. Donovan,” or “supervised,” which might indicate that Dr. Donovan was involved in such procedures. *Id.* Notably, DOH itself (with respect to *physician* claims for Medicaid payment) has identified language indicative of physical presence: “I performed a history and physical examination of the patient...” or “I saw the patient and evaluated his progress ...” or “I saw the patient with the resident/intern ...”<sup>16</sup> June 2009 Medicaid Update. Such first-person statements are a far cry from the objective descriptions Relator cites, and are more plausibly construed as normal supervisory notes than false representations of physical presence.

**B. The Allegations Concerning LRP s Fail to State a Claim on Which Relief May Be Granted.**

Relator alleges that two PMSR program residents did not obtain, or failed to renew, the LRP that New York State Education Law § 7008 requires of podiatry residents in hospital settings<sup>17</sup> and that, accordingly, claims for payment for services involving these residents constitute false claims to the Medicare and Medicaid programs.<sup>18</sup> Am. Cplt. ¶¶ 65-76, 72. As previously discussed (*supra*, at pp. 14-15), Relator’s attempts to state a claim for FCA liability on the basis of any *express* false certification theory necessarily fail. Thus, we are left with the theory that Medicare and Medicaid claims allegedly submitted by Defendants for activities in

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<sup>16</sup> Medicare advises use of similar language. Medicare Claims Processing Manual, Ch. 12, § 100.1.1.

<sup>17</sup> Quinton Yeldell allegedly had no LRP from July 1, 2011 until his termination in March of 2012; Michael Walters allegedly had none from July 30, 2010 through June 30, 2011. Am. Cplt. ¶¶ 68, 69, 72.

<sup>18</sup> Relator refers to several procedures in which Yeldell or Walters “assisted,” but does not identify whether any associated patients were Medicare or Medicaid participants. Am. Cplt. ¶¶ 70, 75. Relator also alleges on unspecified “information and belief” that each resident “also treated patients in the Clinic, Emergency Room and on an inpatient basis during the same period.” Am. Cplt. ¶¶ 70, 75. The Amended Complaint fails to identify what, if any, claims were billed for these particular services, or by whom.

which these residents were involved were *impliedly* false because (1) residents' compliance with the state LRP requirement is a material factor in whether Medicare or Medicaid will pay for services in which they participate; and (2) Medicare will not make GME payments to hospitals with respect to residents who lack a New York State LRP.

Relator's implied certification theory fails as well, however, under both prongs of the *Universal Health* test: she neither alleges that any claims (hospital, professional, or GME) make representations as to the particular residents who are said to lack LRPs, nor does she allege any facts to demonstrate that Medicare or Medicaid would refuse to pay for services in which a resident lacking an LRP participated. Absent such a representation, there can be no *misrepresentation*, and the question of materiality is not even reached. *Universal Health*, 136 S. Ct. at 2000-01.<sup>19</sup> But even were there such representation, as discussed below, New York's LRP requirement for podiatry residents is simply not material to whether Medicare or Medicaid would pay for services in which such residents participated, and thus, no FCA liability can attach merely because some such resident's LRP is lacking. *See id.* at 1996 ("A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act").

#### **1. Lack of LRP by a Resident Has No Bearing on Payment for Dr. Donovan's Professional Services.**

Relator's allegations concerning two residents' lack of an LRP fail to state a claim with respect to Dr. Donovan's professional services. Podiatrist professional services in a hospital setting are simply not a covered service separately payable by Medicaid (*supra*, pp. 10-11, 28-29). For Medicare, no claim for professional services is specifically alleged in the Amended

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<sup>19</sup> Compare, *Universal Health*, 136 S. Ct. at 2000 ("staff ... misrepresented their qualifications and licensing status to the Federal Government to obtain individual National Provider Identification numbers [NPIs]," which NPIs were included on the claim to identify the individual provider of the service).

Complaint. But even assuming, arguendo, that a bill was submitted to Medicare for Dr. Donovan's professional services in which a resident participated, payment of such claim would depend on whether on such occasion Dr. Donovan satisfied the physical presence requirement of the Teaching Physician Rule. *See* 42 C.F.R. § 415.172(a). Whether the resident had, or did not have, an LRP would be immaterial to the payment decision.

**2. Lack of LRP Is Immaterial to Payment for Hospital Services.**

Although Relator alleges violations of N.Y. Educ. Law § 7008, that LRP requirement is not a Medicare or Medicaid law, nor is it even applicable to Defendants; it applies on its face to *podiatry residents* seeking to participate in a hospital-based residency program. Since the law does not apply to Defendants, its alleged violation by two residents cannot support an FCA claim against Defendants. *See Bishop*, 823 F.3d at 48 (regulation limiting authority of Federal Reserve to lend to banks “[b]y its plain terms, [] does not apply to the banks themselves” and cannot support an implied certification claim). Relator alleges no factual basis for concluding that Medicare or Medicaid refuse to reimburse for hospital services in which a resident participated who did not possess an LRP. *See Universal Health*, 136 S. Ct. at 2003. And even if residents' Education Law obligation in this respect were appropriately converted into an obligation upon hospitals, this is exactly the type of rule that prompted the Supreme Court, in justifying the stringent materiality requirement for FCA liability, to comment in *Universal Health* that “[t]he False Claims Act is not ‘an all-purpose antifraud statute,’ [citation omitted], or a vehicle for punishing garden-variety breaches of contract or regulatory violations.” *Id.* at 2003.

**a. A Residents' LRP Status Is Immaterial to Medicare's Decision to Pay for Hospital Services.**

Relator has cited no applicable Medicare law or regulation that states that a resident's compliance with the LRP requirement is a factor relevant to payment for hospital services.

Relator's citations to the contrary are simply inapposite. Relator cites the definition of covered "inpatient hospital services," which includes "[m]edical or surgical services provided by certain interns or residents-in-training," to the extent they are in approved medical, dental or podiatric residency training programs. Am. Cplt. ¶ 35; 42 C.F.R. §§ 409.10(a)(7), 409.15. But these provisions actually confirm that inpatient services furnished by residents in approved residency programs, such as CIH's PMSR program, are within the scope of the Medicare inpatient hospital services benefit, without regard to any State permit requirements. Relator cites no authority for the proposition that Medicare payment for a patient's hospital stay must be denied if a resident whose training included involvement in that patient's treatment failed to comply with the LRP requirement. Indeed, payment for resident activities is not even part of the Medicare rate paid for particular inpatient hospital services, but instead is reimbursed as a cost of medical training through separate GME payments to the hospital. *See*, pp. 7-8, *supra*.

Relator also cites *nothing* to support her allegation that Medicare would decline reimbursement for outpatient hospital services involving a resident who lacked a New York State LRP. As with inpatient services, the costs of employing such residents are not even a component of Medicare's outpatient hospital rates. *See* 42 C.F.R. § 419.2(c)(1) (costs of direct GME activities are "excluded from the hospital outpatient prospective payment system"). Instead, the federal Medicare agency, in adding 42 C.F.R. §410.27(a)(1)(v) effective January 1, 2014, confirmed that during the period at issue here, the Medicare program routinely paid, and determined it did not have the authority to deny payment made for, outpatient hospital services involving non-physician practitioners who did not have applicable State law qualifications. *See, e.g.*, 78 Fed. Reg. 74826, 75059-75061 (Dec. 10. 2013). In light of this, no hospital would have had reason to know that Medicare would consider a resident's non-compliance with his state

LRP requirement material to payment. Compare *Universal Health*, 136 S. Ct. at 2003 (“know[ledge] that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement” is indicative of materiality with respect to FCA liability).

**b. Residents’ LRP Status Is Immaterial to Medicaid’s Decision to Pay for Hospital Services.**

Relator attempts to support her point that “services furnished by non-permitted residents are non-reimbursable under Medicaid” (Am. Cplt. ¶ 67) by quoting from a general State Manual that identifies “medical care provided by qualified ... practitioners within the scope of their practice as defined by State Law” as a Medicaid covered service – *i.e.*, a service for which a discrete Medicaid payment is available. New York State Medicaid Program Information for All Providers – General Policy, at 7 (Oct. 20, 2011).<sup>20</sup> But residents are not “practitioners” for whose services a Medicaid payment is available – *regardless* of the resident’s LRP status.<sup>21</sup> Instead, the same manual section separately identifies “inpatient care in hospitals” and “outpatient hospital and clinic services” as covered services; it is these *hospital* benefits, rather than the care by “practitioners” benefit, that encompass services furnished by residents in a hospital setting. The cited language does not address residents, or their LRP requirement, at all.<sup>22</sup>

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<sup>20</sup> [https://www.emedny.org/ProviderManuals/AllProviders/PDFS/Information\\_for\\_All\\_Providers-General\\_Policy.pdf](https://www.emedny.org/ProviderManuals/AllProviders/PDFS/Information_for_All_Providers-General_Policy.pdf) (last visited June 9, 2016).

<sup>21</sup> See New York State DOH Medicaid Update Vol. 30, No. 8 (Aug. 2014), [https://www.health.ny.gov/health\\_care/medicaid/program/update/2014/2014-08.htm#ord](https://www.health.ny.gov/health_care/medicaid/program/update/2014/2014-08.htm#ord) (last visited June 8, 2016) (only licensed providers are “eligible for enrollment as NYS Medicaid providers”); *see also* 18 N.Y.C.R.R. § 504.1(b)(1) (only enrolled providers receive Medicaid payment); March 2010 Medicaid Update (Medicaid payment to *interns and/or residents* is not permitted but payments for supervising and/or teaching physicians may occur instead).

<sup>22</sup> Relator also cites a definitional section which states that hospital outpatient departments “must comply with all applicable provisions of State law” (Am. Cplt. ¶ 37). New York State Medicaid Program Policy Guidelines Manual for Article 28 Certified Clinics, at 39 (June 1, 2007), [https://www.emedny.org/ProviderManuals/Clinic/PDFS/Clinic\\_Policy\\_Guidelines.pdf](https://www.emedny.org/ProviderManuals/Clinic/PDFS/Clinic_Policy_Guidelines.pdf) (last visited June 9, 2016). But nothing in this section suggests that a *resident’s* failure to obtain an LRP would constitute

Similarly, Relator cites to inapplicable Manual provisions that exclude from Medicaid coverage services that “fail to meet existing standards of *professional practice*, [or] are currently *professionally unacceptable*,” citing one example thereof – “*Practicing a profession* fraudulently beyond its authorized scope, including the rendering of care, services or supplies while one’s license to practice is suspended or revoked.” *Id.*, pp. 23-25. These provisions speak only to *professional practice* (e.g., physician practice); residents functioning within GME programs, with or without LRPs, are not engaged in *professional practice*, as evidenced by the fact that their services are not billable to Medicaid as *professional services*; they are simply being trained. Indeed, a purpose of residency programs is to train residents in *how* to practice their profession when they become prepared to do so. Thus, Relator has not plausibly alleged that a resident without an LRP, and/or the hospital in which he trains, has committed an unacceptable practice within the meaning of this Manual provision, let alone one that is material to Medicaid payment as would be required to properly plead an FCA claim.

### **3. Medicare GME Funding to Hospitals Is Not Conditioned on Residents’ LRP Status.**

Relator also alleges that 42 C.F.R. § 413.75(b) effectively prohibits Medicare GME reimbursement for services performed by residents lacking an LRP. Am. Cplt. ¶ 66. That regulation, however, makes no mention of a resident’s compliance with State permit requirements; it merely defines a resident, for purposes of calculating a hospital’s GME payments, as “one who is formally accepted, enrolled, and participating in an approved medical residency program” *Id.* Both residents met these requirements throughout the periods at issue.

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noncompliance with state law by the *hospital*, and there is no allegation that would lead to such an inference. Moreover, this expansive statement is insufficient to indicate that Medicaid would deny a hospital payment due to a given resident’s non-compliance with his/her LRP requirement. See *Universal Health*, 136 S. Ct. at 2002 (“[B]illing parties are often subject to thousands of complex statutory and regulatory provisions. Facing False Claims Act liability for violating any of them would hardly help would-be defendants anticipate and prioritize compliance obligations”).

Am. Cplt. ¶¶ 68, 72. State permit documentation is not even among the numerous categories of materials the Medicare agency requires to be submitted as part of the Medicare cost report for GME funding. 42 C.F.R. § 413.75(d). Therefore, a GME reimbursement claim does not include any representation that the residents have any requisite State permits. Thus, Relator does not, because she cannot, allege any facts to show that Medicare would, or even could legitimately, refuse GME funding to a program because certain of its residents lack their LRPs.

**C. The Amended Complaint Fails to Plausibly State a Claim That the PMSR’s Alleged Violations of CPME Program Standards Rendered Its Claim for GME Funding False or Fraudulent.**

Hospitals receive GME funding from Medicare and Medicaid to offset costs related to “approved residency programs.” Although Relator acknowledges that the PMSR program was, and is, approved by the CPME, she claims that the compliance and supervisory issues she has alleged mean that the program “cannot reasonably be deemed ‘approved’” for GME payment purposes. Am. Cplt. ¶ 95. Relator further claims that Defendants misled the CPME as to these defects, and that only through such deception was the PMSR program able to maintain its approved status. These allegations are either wrong or based on mere speculation and conjecture.

With respect to *Medicaid* GME payments, Relator’s claims about fraud on the CPME are inapposite. Contrary to Relator’s allegations (Am. Cplt. ¶¶ 39, 40, 42, citing N.Y. Pub. Health Law § 2807-c and 10 N.Y.C.R.R. Part 86-1), no law or regulation conditions Medicaid GME reimbursement to hospitals on CPME or other accrediting body approval of a residency program.

Medicare, on the other hand, makes GME payments only for costs related to “approved residency programs,” including podiatry programs approved by the CPME. 42 C.F.R. § 413.75(b); 42 C.F.R. § 415.152; *see also* 42 C.F.R. § 412.105(f)(1)(i)(A). It is undisputed that at all times relevant to this litigation, the PMSR program was approved by the CPME, and that it has remained so. Medicare laws and regulations accept and defer to the determinations of

associations of health professionals such as the CPME as to which programs are approved. Am. Cplt. ¶ 95. If any Defendant made the certification to Medicare alleged by Relator (Am. Cplt. ¶ 41) – the Amended Complaint does not specify who, or whether any Defendant, so certified – such certification was truthful: the CPME did in fact approve CIH’s PMSR program.

As Relator acknowledges, the CPME has a formal process by which to address concerns regarding needed program improvements or disciplinary actions, short of withdrawing approval. Am. Cplt. ¶ 45. Even when approval is in jeopardy, the CPME can send a “strong warning” by imposing a probationary period during which a program may remedy its deficiencies.<sup>23</sup> CPME Complaint Procedures list six different possible adverse actions, in order of potential severity, that can be taken when a complaint alleging noncompliance is filed against a program, only the last of which might encompass withdrawing approval.<sup>24</sup> Even if Relator’s allegations of programmatic deficiencies were true and the underlying issues concealed from the CPME, there is thus no logical basis for assuming that the program would have lost its approval.

This is all the more true here, where Relator alleges that the CPME was *aware of Relator’s “allegations concerning core deficiencies”* but *nevertheless approved* the PMSR program. Am. Cplt. ¶ 96. Relator writes off this knowledge and determination, alleging that CIH misled the CPME in its investigation – without specifying who engaged in any such duplicity, and with what assistance from any Defendant, or when and how it occurred. *Id.* Relator would single-handedly rewrite the CPME’s process and second-guess its judgment, and would have this Court be an arbiter of whether the CPME was misled or acted inappropriately in approving the

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<sup>23</sup> CPME 330, Procedures for Approval of Podiatric Medicine and Surgery Residencies (July 2015), at <http://apma.files.cms-plus.com/CPME%20330%20final%20June%202015.pdf> (last visited June 9, 2016).

<sup>24</sup> These include taking no further action, making recommendations, “suggesting or requiring changes in procedures, adherence to laws, or compliance with CPME standards, requirements, criteria, or procedures,” and other actions deemed appropriate. CPME 925, Complaint Procedures, (Jan. 2008) <http://www.cpme.org/files/FileDownloads/21651.pdf> (last visited June 9, 2016).

PMSR program. This is not a cognizable basis for an FCA claim. *See, e.g., United States ex. rel. Ortega v. Columbia Healthcare, Inc.*, 240 F. Supp. 2d 8, 20 (D.D.C. 2003) (rejecting FCA claims alleging a hospital fraudulently obtained accreditation in order to participate in Medicare); *U.S. & State v. Bushwick United Hous. Dev. Fund Corp.*, 977 F. Supp. 2d 235, 240-41 (E.D.N.Y. 2013) (dismissing action alleging day care center violating child-to-adult ratio limits should have lost its license and thereby its government funding, where regime “does not require automatic denial or revocation” for noncompliance: “Once the federal courts start addressing the issue of which violations are ‘serious enough’ to give rise to a false claim … they will have effectively taken over the administrative function.”).

For these reasons, Relator’s claims that hospital GME funding was falsely and fraudulently obtained are without merit.

### **III. CLAIMS AGAINST NYC HEALTH + HOSPITALS UNDER THE NYFCA SHOULD BE DISMISSED FOR LACK OF JURISDICTION.**

Relator’s claims against NYC Health + Hospitals under the NYFCA (Am. Cplt. ¶¶ 130-52) must be dismissed because it is not a “person” that can be held liable under the statute. The NYFCA, N.Y. State Fin. Law § 189, establishes liability for any “person” who commits certain acts. “Person” is defined in § 188 as “any natural person, partnership, corporation, association or any other legal entity or individual, *other than the state or a local government*,” where “[l]ocal government” is defined to include “any New York … *local public benefit corporation* or other municipal corporation.” *Id.* NYC Health + Hospitals was created by an act of the New York State Legislature in 1969, as a “body corporate and politic constituting a public benefit corporation.” N.Y. Unconsol. Laws § 7384; *see also Brennan v. City of New York*, 59 N.Y.2d 791, 792 (1983) (“The New York City Health and Hospitals Corporation is a public benefit corporation”). Because NYC Health + Hospitals is a public benefit corporation, it is not a person

under the NYFCA. Thus, Relator's claims against it under the NYFCA must be dismissed for lack of subject matter jurisdiction.

**IV. THE COURT SHOULD DISMISS RELATOR'S CLAIMS WITH PREJUDICE.**

If the 152-paragraph Amended Complaint demonstrates anything, it is that Relator would have referenced particular false bills if she knew of any. She is unaffiliated with CIH and in no position to acquire new information to support her allegations. Accordingly, the Court should dismiss the Amended Complaint in its entirety with prejudice. *See Americare, Inc.*, 2013 WL 1346022 at \*6 (dismissal without leave to replead); *Johnson*, 686 F. Supp. 2d at 270 (same).

**CONCLUSION**

For the reasons set forth herein, Defendants respectfully urge the Court dismiss the Amended Complaint in its entirety with prejudice, and for such other and further relief as the Court deems just and proper.

Dated: New York, New York  
July 29, 2016

KATTEN MUCHIN ROSENMAN LLP

By: /s/ Joseph V. Willey  
Joseph V. Willey  
Alan J. Brudner  
575 Madison Avenue  
New York, New York 10022  
Phone: (212) 940-8800  
Fax: (212) 940-8776  
joseph.willey@kattenlaw.com  
alan.brudner@kattenlaw.com  
*Attorneys for Defendants*